Testimony
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CDC's Influenza Vaccine Efforts

Statement of

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Mr. Chairman and members of the committee, I am pleased to be here today to discuss the Centers for Disease Control and Prevention's (CDC) efforts to address the current influenza vaccine shortage. Vaccination is the primary strategy for protecting individuals who are at greatest risk of serious complications and death from influenza. In the face of this season's influenza vaccine shortage, CDC, state and local public health practitioners, and vaccine manufacturers have worked tirelessly to protect our most vulnerable populations. I want to especially recognize the good faith, cooperation, and the significant contribution of Aventis Pasteur to ensure that the available supply of influenza vaccine goes to those people who truly need it most this season. And we must not forget the important service of immunization providers on the front lines in doctors' offices, health clinics, grocery stores, and pharmacies working to prioritize, deliver, and administer vaccine so that it reaches high-risk individuals.

I also want to thank the nation's health protection heroes, those people across the country who are stepping aside and not getting vaccinated so that those at high-risk will be protected this influenza season. I particularly appreciate the cooperative and collaborative spirit of Americans who have pulled together to help us meet this challenge head on.

I would be remiss, however, if I failed to mention the tremendous progress we have made. In the last four years, the Department of Health and Human Services has begun investing in new technologies, securing more vaccines and

medicines, and preparing stronger response plans. We have made significant investments in protecting against the flu, including increases for CDC influenza funding ($17.2 million to $41.6 million, 242%) and creation of Strategic Reserves/Stockpiles ($0 to $80 million). These investments are further detailed as follows:

- **New Technologies:** In each of the last two budgets, HHS has asked for $100 million to shift vaccine development from the cumbersome egg-based production to new cell-culture technologies, as well as to provide for year-round availability of eggs to provide for a secure supply and surge capacity. These new technologies will help produce flu vaccine more efficiently and provide more adaptability to unexpected problems or losses in production.

- **Creating the Nation's First Stockpiles of Medicines:** For the first time ever, we have created stockpiles of both influenza vaccine and antiviral medications. The Department invested $40 million in 2004, and is planning to invest another $40 million in 2005, to stockpile influenza vaccine through the Vaccines for Children Program. We invested $87.1 million to stockpile 2.3 million doses of Tamiflu; we invested $34 million on Rimantadine capsules to treat 4.25 million adults and on Rimantadine syrup to treat 750,000 kids. These stockpiles give the government new

ability to protect the most vulnerable, and respond effectively when there is a shortage of vaccine.

- **Pandemic Flu Plan:** In August, Secretary Thompson unveiled the department's draft Pandemic Influenza Response and Preparedness Plan. This plan outlines a coordinated national strategy to prepare for and respond to a flu pandemic. One of the first internal committees the Secretary created when he came to HHS was on the pandemic flu.

- **Improving Access by Covering Costs:** The Centers for Medicare & Medicaid Services (CMS) has more than doubled the payment rates for the vaccine and its administration since 2000. In 2004, CMS is paying $18.30 for the vaccine and administration -- up from $8.92 in 2000. This is helping to ensure the vaccine is affordable for patients to get and cost-effective for providers to administer.

PREPARATIONS FOR THE 2004-05 INFLUENZA SEASON

Currently, three vaccine manufacturers are licensed to produce influenza vaccine for use in the United States; two produce inactivated vaccine delivered by intramuscular injection and one makes a live vaccine delivered by nasal spray. The inactivated vaccine, commonly referred to as the “flu shot,” represents the majority of influenza vaccine available in the United States and is licensed for use in all individuals 6 months of age and older. The nasal spray vaccine is a

new vaccine, introduced to the U.S. market for the 2003-04 influenza season, and is licensed for use in healthy persons between 5 to 49 years of age. All influenza vaccine is produced, and the vast majority is distributed and administered, by the private sector. Because of the time required to obtain adequate supplies of eggs in which influenza virus is grown, manufacturers must predict demand and decide how much of the vaccine to produce six to nine months before the influenza season begins. Because influenza vaccine production is a complicated process involving several steps over a long period of time, it was not possible to begin new production of influenza vaccine after the shortage was announced.

CDC and the Department of Health and Human Services (DHHS) took several steps to prepare for the 2004-05 influenza season, including specific action to prevent a late-season surge in vaccine demand such as the one experienced last year in which the demand for influenza vaccine in the United States exceeded what had been experienced in previous influenza seasons. In preparation for the 2004-05 influenza season:

- Vaccine manufacturers licensed to produce influenza vaccine for the U.S. market anticipated producing a supply of approximately 100 million doses of inactivated influenza vaccine for this year, significantly more doses than have ever been produced for the United States.

- CDC planned to establish a stockpile of 4.5 million doses of influenza vaccine for the nation's children. The primary purpose of the stockpile was to meet late-season, unmet pediatric demand as we are currently experiencing this year.

- CDC augmented domestic influenza surveillance this season with surveillance for pediatric hospitalizations and pediatric mortality reporting. In addition, CDC is expanding its capacity for rapid detection of new strains of influenza viruses and has funded a study to prospectively evaluate vaccine effectiveness during this winter's influenza season.

As noted previously, DHHS is supporting activities designed to ensure year round influenza vaccine capacity and to incentivize the accelerated development, licensing and domestic production of cell-culture influenza vaccines. The President's FY 2004 and FY 2005 budgets each proposed $100 million for these efforts. A contract for egg surge capacity worth about $10 million has already been awarded. Negotiations are currently underway for tissue culture vaccine research and development contracts.

In addition, DHHS has expanded biosurveillance activities so that scientists can more rapidly detect changes in circulating influenza viruses and determine potential strains for vaccines. DHHS is collaborating with the Department of

Agriculture and the Department of State to further enhance surveillance efforts in Asia, in both human and animal populations

CDC RESPONSE TO THE 2004-05 INFLUENZA VACCINE SHORTAGE

On October 5, 2004, Chiron Corporation notified DHHS that none of its influenza vaccine (Fluvirin®) would be available for distribution in the United States for the 2004–05 influenza season. The company indicated that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, where Chiron's Fluvirin vaccine is produced, suspended the company's license to manufacture Fluvirin vaccine in its Liverpool facility for three months. This action prevented the release of its vaccine for this influenza season. This action reduced by approximately 46 to 48 million doses, or almost one-half, the expected supply of inactivated influenza vaccine available in the United States for the 2004–05 influenza season.

Following the Chiron announcement, DHHS and its agencies, including CDC, took immediate action in response to the loss of this vaccine supply. CDC responded quickly and effectively to the influenza vaccine shortage by activating the Director's Emergency Operations Center (DEOC) Influenza Task Force to coordinate the overall CDC response. CDC's immunization, infectious disease, and other experts are working collaboratively across the agency to address areas such as clinician policy and guidelines, vaccine supply and distribution,

healthcare impact, logistics, influenza assessment and surveillance, informatics, and communications. These dedicated public health professionals have worked tirelessly to protect the nation's health during this influenza vaccine shortage.

CDC is working hard to target the distribution of the remaining inactivated vaccine towards the most vulnerable populations; identify available vaccine from other countries that might be used this season; reinforce the agency's supply of antiviral medications in the Strategic National Stockpile and provide recommendations for their use during this influenza season; develop strategic communication messages to facilitate the public health response to the shortage; enhance surveillance for influenza disease and outbreaks so that early, effective responses can be delivered; and implement a comprehensive monitoring and evaluation system to assess the effectiveness of the strategies to target vaccine to high-risk groups and the response to influenza outbreaks.

Interim Influenza Vaccination Recommendations for the 2004-05 Season

On October 5, in coordination with the Advisory Committee on Immunization Practices (ACIP), CDC issued interim recommendations for influenza vaccination during the 2004-05 season. The interim recommendations identify the priority groups of people that should receive the limited supply. These include people who are most vulnerable to develop serious complications and even death from influenza: adults 65 years of age and older, children 6 to 23 months of age, individuals with certain chronic underlying medical conditions, pregnant women,

residents of nursing homes and long-term care facilities, and children on chronic aspirin therapy. In addition, the ACIP recommended vaccination for individuals who might otherwise spread influenza to high-risk individuals, including household contacts of infants under 6 months of age and healthcare workers providing direct, hands-on patient care. These interim recommendations take precedence over earlier recommendations.

Influenza Vaccine Supply and Allocation Plan

Following the Chiron withdrawal, Aventis Pasteur announced that it would work with CDC to develop a plan to target the remaining available influenza vaccine toward providers serving the populations at greatest risk for serous complications from influenza. I commend Aventis Pasteur for its leadership and willingness to join us in addressing this public health concern. In addition, state and local health officials have worked together with the CDC and Aventis Pasteur to assure the most equitable and efficient means of distribution of the remaining, limited supply of vaccine across the Nation. The significant contributions and leadership of these public health professionals has enabled our nation to respond effectively to this public health challenge.

As of October 5, Aventis Pasteur had planned to produce over 50 million doses of inactivated influenza vaccine for the 2004-05 influenza season. At that time, approximately 33 million doses had already been shipped to pediatricians, primary care and other office-based physicians, public health providers, and

other community-based vaccine providers. Approximately 14.2 million of the remaining 22.4 million doses of unshipped vaccine were allocated for redistribution through Aventis Pasteur contracts with providers serving the high-priority populations. On October 19, 2004, Aventis Pasteur announced that it would produce an additional 2.6 million doses of vaccine that would be available in January 2005. With these additional doses, their total of inactivated influenza vaccine for this season is expected to exceed 58 million doses, of which 10.3 million are still to be produced and distributed in the coming weeks, as of November 9, 2004.

CDC and Aventis worked to identify a number of orders placed with Aventis Pasteur and the seven distributors through which Chiron vaccine is shipped, that were intended for providers known to serve substantial numbers of high-risk patients. These included doses ordered by:

- State and local health departments;
- The Vaccines for Children Program;
- Children's providers;
- Healthcare providers for Aventis Pasteur's preservative-free influenza vaccine (licensed for use with children 6-35 months of age);
- The Department of Veterans Affairs and the Indian Health Service;
- Long-term care facilities and acute care hospitals;
- The Visiting Nurses Association of American (VNAA); and
- The Department of Defense.

Every effort has been made to provide vaccine to as many providers serving high-risk populations as possible in a timely fashion.

CDC, state and local health officials, Aventis Pasteur, and Chiron vaccine distributors worked together to canvass the orders placed with the seven Chiron distributors, with an emphasis on orders placed by providers likely to be serving a high number of priority patients; and surveyed long-term care facilities to identify those facilities that ordered Chiron vaccine, either directly or via a sub-distributor or intermediaries such as pharmacies.

The CDC implemented a secure web-based application, the Flu Vaccine Finder that is available to state health officials to identify all doses of inactivated influenza vaccine shipped to their state during the 2004-05 season. State health officials and CDC have worked together, in consultation with local health departments, to develop a formula for the equitable distribution of the remaining influenza vaccine to be shipped. This formula took into account the population of high-risk individuals in each state and the number of influenza vaccine doses that have already been shipped to each state.

Of the limited number of licensed doses of vaccine that remains to be shipped, there is agreement that all public sector orders that were submitted on federal, state, and multistate contracts will be filled. CDC estimates this to be

approximately 11.9 million doses total, with 3.4 million of those doses to complete the public sector orders that were submitted on federal, state and multistate contracts. CDC has asked state health officials to work collaboratively with local health departments and private immunization providers to guide the final allocation of the remaining approximately 7.2 million adult doses. State and local health officials are best suited to develop and implement this second phase of the vaccine allocation plan. Another 1.2 million doses of pediatric vaccine will be allocated to states using the same approach. State and local health officials have the most accurate and comprehensive understanding of the needs within their jurisdictions, the necessary relationships with public and private health care providers to target vaccine to reach the most vulnerable populations in their states, and the authority to ration in times of shortage.

Price Gouging

Finally, there is the issue of alleged price gouging. CDC is very concerned to learn of reported incidences of price gouging during this particularly challenging time. In response to the reports of alleged price gouging, the Secretary sent a letter on October 14, 2004, to each state urging them to thoroughly investigate reports of price gouging involving influenza vaccine and to prosecute to the full extent of the law those found to be involved. CDC is also collecting reports on price gouging and sharing them with the National Association of Attorneys General and state prosecutors.

Additional Sources of Influenza Vaccine

Approximately 3 million doses of the intranasally administered, live, attenuated influenza vaccine, FluMist, are being produced for the 2004-05 season. This vaccine is encouraged for use among healthy persons ages 5–49 years who are not pregnant. This includes healthcare workers (except those who work with severely immunocompromised patients in special care units) and household contacts of infants less than 6 months of age. CDC is making people aware of this alternative to inactivated influenza vaccine.

Several manufacturers of influenza vaccines licensed for use in Europe and Canada have vaccine, which is under review for use in the United States as Investigational New Drugs (IND). Because these vaccines are not currently licensed in this country, they will have to be administered under special protocols with written consent. CDC is studying the feasibility of use of IND vaccine as it is developing protocols for vaccine use and the U.S. Food and Drug Administration (FDA) is inspecting the manufacturing plants. As many as 5 to 6 million doses of vaccine may be available from these manufacturers, although even if approved for an IND, we would not expect delivery of most of this vaccine until December and January.

Antiviral Medications and Pneumococcal Vaccine

Influenza antiviral medications are an important adjunct to influenza vaccine in the prevention and treatment of influenza. CDC has developed interim

recommendations on the use of antiviral medications for the 2004-05 influenza season. The interim recommendations were developed to reduce the impact of influenza on persons at high risk for developing severe complications secondary to infection. The recommendations are not intended to guide the use of these medications in other situations, such as outbreaks of avian influenza.

Influenza antiviral medications have long been used to limit the spread and impact of institutional influenza outbreaks. They are also used for treatment and chemoprophylaxis (prevention) of influenza in other settings. In the United States, four antiviral medications -- amantadine, rimantadine, oseltamivir, and zanamivir -- are approved for treatment of influenza. When used for treatment within the first two days of illness, all four medications are similarly effective in reducing the duration of illness caused by Strain A influenzas by one or two days. Only three antiviral medications (amantadine, rimantadine, and oseltamivir) are approved for prevention of influenza.

CDC encourages the use of amantadine or rimantadine for prevention and use of oseltamivir or zanamivir for treatment of those who are ill from influenza, as supplies allow. People who are at high risk of serious complications from influenza may benefit most from antiviral medications.

The United States has a supply of influenza antiviral medications for both adults and children stored in the Strategic National Stockpile for emergency situations. There are 1,336,380 regimens of rimantadine tablets, 60,000 regimens of

rimantadine syrup, 859,993 regimens of oseltamavir capsules, and 110,336 regimens of oseltamavir suspension. DHHS has procured additional supplies of antiviral medications, and shipments are arriving weekly. By the end of December, the federal stockpile of antiviral drugs will include enough doses of rimantadine for 4.25 million adults and 750,000 children and enough oseltamivir for 2.3 million people. Rimantadine will be made available to states and territories for use in outbreak settings, as might occur in a hospital or long-term care facility, if commercially available supplies become depleted nationwide. Because oseltamavir is the only antiviral drug known to be effective against avian influenza, we will work to maintain the supply of oseltamavir in reserve to be used in the event of an influenza pandemic.

In addition, Merck & Co. is tripling its production of pneumococcal vaccine used to prevent pneumococcal disease, which is a common complication of influenza. Pneumovax is not a substitute for the influenza vaccine, but can help prevent influenza complications. Many people who fall into the priority groups for the influenza vaccine should also get the pneumonia vaccine.

Communicating the Public Health Response

Since the release of the interim influenza vaccination recommendations, CDC has used a variety of channels to communicate comprehensive information about the influenza season, the recommendations for priority groups for vaccination, the status of the vaccine supply, and alternative methods of reducing the

transmission and severity of disease. Relevant and timely communications with the public, health care professionals and policy makers is a critical component of the public health response to the current influenza season and the vaccine shortage.

CDC's influenza web portal (http://www.cdc.gov/flu) features updated information and materials for the public and clinicians. Materials are available in ten languages (in addition to English) as well as in low-literacy formats. As the public health response to the vaccine shortage has evolved, this website has become a vital resource receiving 300,000 visits per day at its peak, leveling off at over 150,000 visits per day over the past few weeks.

In addition to communications via the Internet, CDC established a new toll-free hotline number, 1-800-CDC INFO, to respond to public and clinician inquiries related to the influenza season and the vaccine shortage. This automated hotline includes selections in English and Spanish, and provides callers with timely and relevant information regarding the influenza season and the vaccine shortage. Since the announcement by Chiron on October 5, 2004, CDC has responded to several thousand inquiries from the public and clinicians through its hotlines.

In collaboration with the non-profit Ad Council, CDC recorded and distributed two audio public service announcements to over 9,000 AM and FM radio stations

across the nation. In addition, two video public service announcements are being developed for distribution before Thanksgiving, and plans are underway to run print ads and articles in the nation's newspapers over the next several weeks.

CDC has also made specific efforts to reach business and educational institutions with critical information about the priority populations recommended for vaccination and alternative methods for preventing transmission of disease in the workplace and educational settings.

THE 2004-05 INFLUENZA SEASON

Influenza seasons are unpredictable. Although epidemics of influenza occur virtually all every year, the particular viruses and the beginning, peak, severity, and length of the epidemic can vary widely from year to year. Before a season begins, it is not possible to accurately predict what the season will look like. However, as of the week ending October 30, 2004, influenza activity in the United States has been low. Forty (0.8%) of 4,736 respiratory specimens tested by U.S. World Health Organization (WHO) and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories were positive for influenza. The proportion of patient visits to sentinel providers for influenza-like illness (ILI) and the proportion of deaths attributed to pneumonia and influenza were below epidemic levels. One state has reported regional influenza activity,

one has reported local activity, and 26 states and New York City have reported sporadic influenza activity. Twenty states and the District of Columbia have reported no influenza activity.

CDC has characterized three influenza viruses collected by U.S. laboratories since October 1, 2004. All were influenza A (H3N2) viruses and were characterized as A/Fujian/411/2002-like, which is an influenza component included in the 2004-05 influenza vaccine.

CONCLUSION

Thank you for bringing additional attention to this important public health issue. CDC is committed to protecting and promoting health for all Americans, preventing disease and disability through public health research and public outreach, and support of important interventions including vaccination. Recognizing the important role of vaccines in protecting the health of all Americans and in preparing for future threats, we will continue to work with our partners to manage the current influenza vaccine shortage and to address our nation's need for access to a safe, reliable supply of influenza vaccine in the future.

Thank you for your interest in this issue and your support of CDC's immunization programs. I will be happy to answer any questions.